



Hospital Products Division

Abbott Laboratories
Dept. 389, Bldg. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

August 13, 1999

Dockets Management Branch (HFA - 305)
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

PEDIATRIC PRIORITY LIST: CITIZEN PETITION

The undersigned submits this petition pursuant to 21 C.F.R. §10.30, pursuant to Food and Drug Administration Docket No. 98N - 0056, "List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population" (May 20, 1999), and pursuant to paragraph V(c) of FDA, "Guidance for Industry: Qualifying for Pediatric Exclusivity under Section 505A of the Federal Food, Drug, and Cosmetic Act" (June 1998), under Section 505A of the Food, Drug, and Cosmetic Act 21 USC §355a, to request the Commissioner of Food and Drugs to add Paricalcitol to the Priority List of Approved Drugs for which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population, as published by FDA under Docket No. 98N - 0056 ("Priority List").

A. Action Requested

The undersigned requests that the Commissioner add Paricalcitol (Zemlar®) to the Priority List.

B. Statement of Grounds

Zemlar® is a synthetically manufactured vitamin D analog that reduces parathyroid hormone (PTH) levels. It is approved in intravenous formulation as Paricalcitol (NDA 20-819).

Zemlar® was approved on April 17, 1998 with an indication for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure. Zemlar is a second-generation vitamin D analog that could be of value in treating those pediatric patients with chronic renal failure, as vitamin D therapy is an essential component of drug therapy in all patients with chronic renal failure. Without vitamin D therapy, patients will develop hyperparathyroidism that could lead to serious complications including renal osteodystrophy. Due to the severity of the indicated disease, additional information on Zemlar® may produce health benefits in the pediatric population.

99P-2850

CPI

6329 99 AUG 17 P1:59

FDA included calcitriol injection (Calcijex®), a vitamin D analog, on the List of Approved Drugs for which Additional Information May Produce Health Benefits in the Pediatric Population. Since Paricalcitol is vitamin D analog as well, it is reasonable to add it to the Priority List to facilitate the issuance of a Written Request for pediatric studies under § 111 (c) of the Food and Drug Administration Modernization Act of 1997, 21 USC § 355a (c).

C. Environmental Impact

The subject matter of this petition is not within any of the categories of action for which an environmental assessment is required pursuant to 21 C.F.R. §25.22, and is exempt pursuant to 21 C.F.R. §25.30(a), in that it is concerned with routine FDA administrative and management activities.

D. Economic Impact

Not requested.

E. Certification

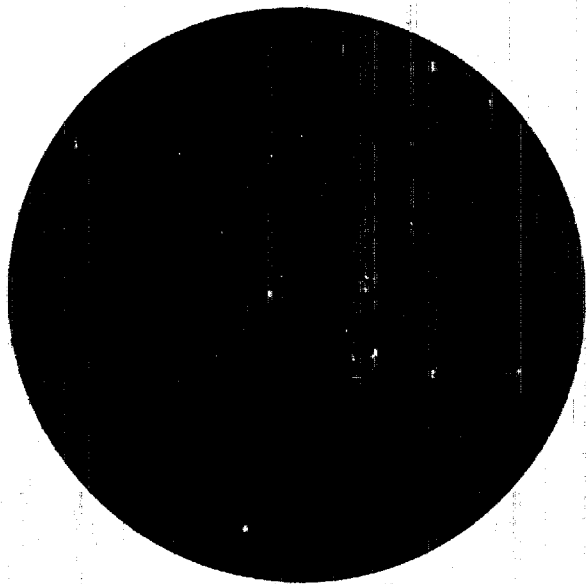
The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Abbott Laboratories

Leslie Koehler /B
Leslie Koehler
Manager, Regulatory Affairs
Hospital Products Division
Phone: (847) 938 - 7873
Fax: (847) 938 - 7867

Federal Express



The World
Letter

Align top of FedEx PowerShip Label here.

DELIVERY SERVICES SATELLITE
ABBOTT LABORATORIES
200 ABBOTT PARK ROAD
ABBOTT PARK IL 60064
(847)937-5985

SHIP DATE: 13AUG99
ACC # 136290363

ACTUAL WGT: 1 LBS SCALE

TO: FDA/Dockets Management Branch (847)937-6449
HFA-305 FDA
5630 Fishers Lane
Room 1061 Dept. of Health and Human
Rockville MD 20852

7400 3143 1790

FedEx

RELEASE # 6180411

REF: 0389 Regulatory Affairs

2DAY

TUE

cad # 0689887 13AUG99

TRK# 7400 3143 1790

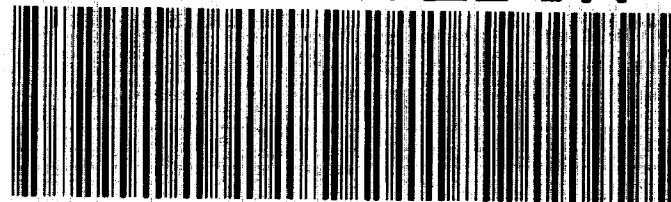
FORM
0201

Deliver by:
17AUG99

20852 -MD-US
RES

IAD AR

LR EDGA



153079-077 GSI 10/98